

REMARKS/ARGUMENTS

Claims 10, 12, 16-20 and 25-34 are currently pending in this application and stand rejected. Claims 10, 18, 25 and 30 have been amended and new claims 35 -37 have been added. Support for the amendments to the claims and the new claims may be found throughout the specification and in the claims as originally filed. For example, support for the amendments to claims 10, 18, 25 and 30 can be found on page 4, lines 7-11. Support for the newly added claims can be found on page 2, lines 13-21 and page 4, line 5. Thus, no new matter has been added by these amendments. Reconsideration and allowance of the claims is respectfully requested in view of the foregoing amendments and the following remarks.

REJECTION UNDER 35 U.S.C. § 102(e)

Claims 18-20 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Birnie et al (Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkyl-N,N-dimethylamine Oxides with Variations in Chain Length, Sept. 2000, Antimicrobial Agents and Chemotherapy, Vol. 44, No. 9, pp. 2214-2517. In order to facilitate prosecution, and while not acquiescing to the Examiner's rejection, Applicant has amended claim 10 to recite that the agent is a viral agent and that the biological source material comprises a biomolecule of interest. Accordingly, withdrawal of this rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 103(a)

Claims 10, 12, 16-20 and 25-34 are rejected under 35 U.S.C. 103(a), as allegedly being obvious over Fonsny et al (US 5,911,915) in view of Rasmussen et al (US 2002/0022649 A1). Applicant traverses this rejection for the reasons provided herein below.

Biological materials are sources for medicinal and industrial intermediates and products. By their nature or method of production, biological materials may contain unwanted agents of viral origin. Prior methods for reduction of unwanted viral activity in biomaterials include the use of heat, steam, pressure, chemical treatments and other methods. These techniques, however, may irreversibly alter the properties of the biological source material or the desired substances to be obtained from the biological source material (see specification, lines 8-25). Accordingly, there was a need for a gentle, non-denaturative

method for reducing unwanted viral activity without damaging the desired molecules or substances of interest. The instantly claimed invention provides such a method.

Fonsny et al relates to a stable cleaning composition formulated for cleaning hard surfaces. In the abstract, Fonsny et al states that the composition is especially effective in disinfecting the surface being cleaned and in the removal of oily and greasy soil without leaving streaks on the hard surface. To achieve those endpoints the Fonsny et al hard surface cleaning composition comprises several components. Fonsny et al does not teach or suggest a method for using specific alkyl amines or amine oxides either alone, or in combination with other agents, for inactivating viral agents in a biological source material (e.g., a host cell, cell supernatant, cell lysate, blood plasma, tissue homogenate, see specification page 2, lines 17-18) comprising a biomolecule of interest. In addition, Fonsny et al does not teach or suggest that a method for using specific alkyl amines or amine oxides either alone, or in combination with other agents, for inactivating viral agents in a biological source material without damaging the biomolecule of interest. Such a teaching is found only in the instant application. Accordingly, Applicant respectfully submits that the Examiner is using impermissible hindsight and request withdrawal of this ground of rejection.

In addition, as discussed above, there was a need for a gentle, non-denaturative method for reducing unwanted viral activity in production of biological materials without damaging the desired molecules or substances of interest. One of ordinary skill in the art would not look to Fonsny et al which relates to a composition designed for cleaning hard surfaces (i.e., removal of oily and greasy soil without leaving streaks on the hard surface) for a solution to a problem in production of biological materials. Fonsny et al is not reasonably pertinent to that problem. Even assuming, *arguendo*, that one of ordinary skill in the art would have modified Fonsny et al for a biological production process, there would have been no reasonable expectation of success. Accordingly, either alone or in combination, Fonsny et al does not render the claimed invention obvious.

Likewise Rasmussen et al relates to granulate and oral solid dosage formulations and a wet granulation method. Rasmussen et al does not teach or suggest a method for using specific alkyl amines or amine oxides either alone, or in combination with a polyol, for inactivating viral agents in a biological source material without damaging the biomolecule of interest. Accordingly, Rasmussen et al does not remedy the deficiencies of Fonsny et al. Withdrawal of this ground of rejection is respectfully requested.

Claims 18-20 and 25-29 are rejected under 35 USC 103(a), as allegedly being obvious over Michaels (US 5,389,676). According to the Examiner, Michaels teaches compositions

comprising surfactants including amine oxides for use in the formulation of disinfectants. Applicant traverses this rejection for the reasons provided herein below.

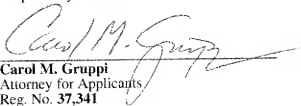
Michaels et al relates to antiinfective water in oil and oil in water emulsions that can be used in cleansers, lotions, ointments, crèmes, jellies and gels that exhibit antiinfective activity (see abstract and column 3, lines 9-12). Michaels et al does not teach or suggest a method for using specific alkyl amines or amine oxides either alone, or in combination with other agents, for inactivating viral agents in a biological source material (e.g., a host cell, cell supernatant, cell lysate, blood plasma, tissue homogenate, see specification page 2, lines 17-18) comprising a biomolecule of interest. In addition, Michaels does not teach or suggest that a method for using specific alkyl amines or amine oxides either alone, or in combination with other agents, for inactivating viral agents in a biological source material without damaging the biomolecule of interest. Such a teaching is found only in the instant application. Applicant respectfully submits that the Examiner is using impermissible hindsight. Accordingly, withdrawal of this ground of rejection is respectfully requested

CONCLUSION

It is believed that claims are now in condition for allowance, early notice of which would be appreciated. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. In the event the United States Patent and Trademark Office determines that an additional extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to Deposit Account No.: 50-4205 ; Reference Number: 2001.689USD1.

January 7, 2010
Organon International Inc.
Patent Department
c/o Schering-Plough Corporation
2000 Galloping Hill Road
K-6-1-1990
Kenilworth, New Jersey 07033-0530
Tel: (908) 298-7486
Fax: (908) 298-5388

Respectfully submitted,


Carol M. Gruppi
Attorney for Applicants
Reg. No. 37,341